Patent
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(Formerly BAF-12802/29)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Bret A. FERREE

Serial No.: 09/638,241

Filed: August 14, 2000

For: METHODS AND APPARATUS FOR TREATING DISC HERNIATION AND PREVENTING THE EXTRUSION OF INTERBODY BONE GRAFT

Group Art Unit: 3773

Examiner: Julian W. Woo

AMENDMENT AND RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed on February 25, 2008, please make the following amendments and consider the following remarks.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 4 of this paper.

CERTIFICATE OF MAILING (37 C.F.R. §1.8)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being electronically transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below via the USPTO EFS-Web filing system.

July 25, 2008
Date of Deposit

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2713715.1

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of the Claims

1-11. (Canceled)

12. (Currently Amended) A method of preventing nucleus pulposus in an intradiscal space from extruding through a defect in the annulus fibrosis, the annulus fibrosis having an outer layer and at least one inner layer, ~~comprising~~ said method consisting essentially of the steps of:

inserting no more than one implant through an elongate tubular member into the defect in the annulus fibrosis;

wherein the implant comprises a flexible device having a structure with at least two appendages joined to form an interior angle and an exterior angle, the interior angle being smaller than the exterior angle during insertion through the elongate tubular member, the appendages being made from a shape-memory material;

advancing the flexible device distally beyond the outer layer in the annulus fibrosis;

expanding the appendages of the flexible device by allowing the device to return to a memorized shape substantially larger than the defect in the outer layer of the annulus fibrosis;;

wherein the flexible device prevents escape of the nucleus pulposus through the defect; and

wherein the interior angle between appendages is larger after deployment than during the step of inserting the implant into the defect.

13. (Previously Presented) The method of claim 12, wherein:

the step of inserting the device includes compacting the device into a compressed form for introduction.

14-15. (Canceled)

16. (Previously Presented) The method of claim 12, wherein the device includes a liquid or gel which solidifies following the insertion of the device.

17. (Previously Presented) The method of claim 16, wherein the device includes a hydrogel or elastomer.

18. (Original) The method of claim 12, wherein the device occludes the defect while allowing compression and distraction of the disc with respect to normal spinal movement.

19-23. (Canceled)

REMARKS

Reconsideration of the rejection set forth in the Office Action dated February 25, 2008, is respectfully requested. Claim 12 has been amended to require the method to consist essentially of certain steps. No new matter was added with this amendment.

Claims 12, 13, and 16-18 were rejected under 35 U.S.C. § 102 for alleged anticipation by Baumgartner. These rejections should be withdrawn for the following reasons.

Applicants have amended claim 12 to require "*said method consisting essentially of the steps of…*" (*See PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) "Typically, 'consisting essentially of' precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.") By previous amendment, claim 12 is additionally limited to the step of "*inserting no more than one implant into the defect in the annulus fibrosis.*" Therefore, the method of claim 12 requires the insertion of only a single implant, *i.e.*, "*no more than one implant*," and does not cover the situation in which multiple implants are inserted into the defect.

Baumgartner, by contrast, requires multiple implants be inserted into the disc space. (See, e.g., Col. 1, lines 41-48 "The object of the invention is to create a universal, simple to apply implant, which can be used as a support member for varied cavities formed at random. This object is achieved in accordance with the invention in that the implant contains at least three elastically deformable support members which can be inserted into the central cavity and can be positioned therein." (emphasis added); *see also* the Abstract "An implant consisting of several

support members (7), which are produced from an elastic plastic, is provided as a replacement for a part, which is no longer capable of bearing loads, or the core region of an intervertebral disk (3). The support members (7) are inserted one after the other into a central cavity (5) ...." (emphasis added))

In fact, Baumgartner believed there would be problems with using only a single implant. (See Col. 1, lines 30-36 "As the surgeon has to work with predetermined implant sizes, he is forced to produce a matching cavity in the core region of the intervertebral disk. The known implant requires a relatively expensive design of the hollow member, in order to guarantee permanent tightness against the egress or fluid, which is required if the implant is to work optimally."). By requiring multiple implants, Baumgartner can fill cavities of varying size by simply inserting additional implants. Therefore, Baumgartner actually teaches away from the step of "*inserting no more than one implant into the defect in the annulus fibrosis*" as required by the amended claims.

The Examiner has taken the position that Baumgartner "indeed discloses a singular (and last) implant *inserted through an elongate tubular member* as claimed, where the implant comprises a flexible device having a structure with at least two appendages (18 or 18') as claimed." (Office Action, Page 3) In other words, the Examiner has taken the position that Baumgartner describes inserting a single implant of a specific type, *i.e.*, an implant having expansion elements as in Fig. 4e, into the disc. As explained above, independent claim 12 has been amended to require that the method consists essentially of the steps of ... "*inserting no more than one implant into the defect in the annulus fibrosis*." Baumgartner requires several

implants. These additional implants required in Baumgartner materially affect the basic properties of the claimed method. Therefore, Baumgartner is outside the scope of claim 12.

Claim 12 is therefore patentably distinct from the cited references. Each of claims 13 and 16-18 are dependent on claim 12 and therefore are patentably distinct from the cited references for the same reasons applicable to claim 12. The rejections under §§ 102 and 103 should therefore be withdrawn.

For all the foregoing reasons, Applicant asserts the claims are in condition for allowance. Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
O'MELVENY & MYERS LLP

Dated: July 25, 2008

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